

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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IN RE: NEW ENGLAND )  
COMPOUNDING PHARMACY, INC. )  
PRODUCTS LIABILITY LITIGATION ) MDL No. 13-2419-RWZ  
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This Document Relates To: )  
)  
All Actions Against Saint Thomas )  
Neurosurgical )  
)

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**ORDER ON PLAINTIFFS' STEERING COMMITTEE'S MOTION TO COMPEL  
AND MICHAEL O'NEAL'S MOTION FOR A PROTECTIVE ORDER**

[Docket Nos. 2437, 2469]

December 22, 2015

Boal, M.J.

The Plaintiffs' Steering Committee ("PSC") moves for an order compelling Michael O'Neal to comply with a subpoena issued to him. Docket No. 2437. O'Neal has cross-moved for a protective order. Docket No. 2469. For the following reasons, this Court grants in part and denies in part the motions and reserves ruling on certain issues.

I. **FACTUAL AND PROCEDURAL BACKGROUND**

This litigation involves claims for wrongful death and personal injury arising out of the administration of an injectable steroid, methylprednisolone acetate ("MPA"), manufactured by New England Compounding Pharmacy, Inc. ("NECC"). The complaints allege, in substance, that NECC produced contaminated MPA that led to serious fungal infections and, in some cases, death. Some plaintiffs have brought claims against numerous non-NECC parties, including the Saint Thomas Entities and Saint Thomas Outpatient Neurosurgical Clinic ("STOPNC"). The plaintiffs allege that STOPNC purchased contaminated injections from NECC and administered

them to patients. They also allege that STOPNC, its employees and agents decided to buy MPA from NECC without undertaking due diligence because it was the cheapest steroid available.

According to the PSC, STOPNC began to purchase MPA from NECC in June 2012. Docket No. 2438 at 2. Facility Director Debra Schamberg, R.N. testified that she and John Culclasure, M.D. were the only individuals at STOPNC who were involved in the company's decision to purchase MPA from NECC. *Id.* Schamberg also testified that other than having a handful of conversations with Dr. Culclasure and reviewing NECC literature stating that NECC had complied with applicable regulations, she did not conduct any due diligence prior to deciding to purchase MPA from NECC. *Id.*

STOPNC does not have an in-house pharmacist. *Id.* at 3. STOPNC contracted with O'Neal, a licensed Tennessee pharmacist, to provide pharmacy expertise. *Id.* According to O'Neal, he was hired as a consultant to evaluate the safety, quality, processes, and appropriateness of healthcare services at STOPNC. O'Neal Aff. at ¶ 3.<sup>1</sup> Specifically, on March 20, 2007, O'Neal entered into a Pharmacy Consulting Contract with STOPNC (the "2007 Contract"). See Docket No. 2439-3 at 7. The 2007 Contract states that O'Neal was hired to perform certain duties, including, inter alia:

- "consultation to all laws, rules and regulations and the administration of such at the Surgery Center;"
- "[a]ssist the center in maintaining its accreditation status by all of its governing bodies;"
- "[d]evelop and aid in maintaining policies and procedures pertaining to any medication brought by or administered at the Surgery Center;"

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<sup>1</sup> "O'Neal Aff." refers to the May 15, 2013 Affidavit of Michael O'Neal, filed in a prior Tennessee state court action, and which can be found at Docket No. 2469-1.

- “establish record-keeping procedures, forms and documents necessary to meet existing accreditation;”
- “[t]o assess the facility at each visit and to perform a monthly unit-check of all areas where medications are administered;” and
- “to perform an bi-annual narcotic inventory.”

Id.

STOPNC began purchasing MPA from NECC in June 2011, and it administered MPA to patients through September 2012. Docket No. 2438 at 4. At some point in or after September 2012, O’Neal and STOPNC entered into a second Consulting Pharmacist Agreement (the “2012 Contract”).<sup>2</sup> See Docket No. 2439-8. The 2012 Contract states that O’Neal’s responsibilities include, inter alia:

- visiting the facility no less than every thirty-five days to perform a routine inspection of all medication storage area;
- representing STOPNC in on-site inspections by state and federal regulatory agencies;
- providing assistance in developing and evaluating appropriate policies and procedures for the safe and effective use of drugs within the facility; and
- assisting “in the development for Quality Improvement Process regarding medication management related procedures and attend[ing] and participat[ing] in the quarterly Quality Improvement Process meetings when applicable and available.”

Id. at 2.

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<sup>2</sup> The 2012 Contract states that it “is made this 1<sup>st</sup> day of September 2012.” Docket No. 2438-8 at 1. However, it appears to have been signed by Schamberg on behalf of STOPNC on September 7, 2012 and by O’Neal on April 4, 2013. Id. at 6.

O’Neal avers that he performs monthly inspections at STOPNC “to evaluate and improve the quality of the healthcare services rendered” at STOPNC and has done so since 2007. O’Neal Aff. at ¶ 13. He also avers that he “ensures” that STOPNC staff members are properly carrying out internal checks concerning their medications; he evaluates and reviews the “method, procedures and/or treatments” at STOPNC “with respect to medications,” he “create[s] reports identifying areas of excellence and those in need of improvement,” which he forwards to (and sometimes discusses with) Schamberg and another individual, Cindy McClendon. O’Neal Aff. at ¶¶ 13-19. Despite the differences between the 2007 Contract and the 2012 Contract, O’Neal maintains that his “relationship with [STOPNC] has been consistent and ongoing since 2007.” O’Neal Aff. at ¶ 3; see also Schamberg Aff. at ¶ 4<sup>3</sup> (“Michael O’Neal’s duties, as reflected in the contracts, have not changed during the entire duration of his relationship with [STOPNC].”).

Schamberg avers that O’Neal ensures that STOPNC is operating in compliance with state and federal laws regarding medications, properly carries out “internal checks regarding its medications,” and reviews STOPNC’s activities relating to the purchase, use and storage of medications. Schamberg Aff. at ¶¶ 14, 15, 17. Schamberg also avers that O’Neal “creates reports identifying areas of excellence and those in need of improvement,” which O’Neal discusses with Schamberg. Id. at ¶¶ 18-20. In addition, she states that, “[a]s a member of [STOPNC’s] Medical Executive Committee, I relay the substance of those reports to the remaining committee members, and we discuss his evaluations and recommendations.” Id. at ¶ 19.

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<sup>3</sup> “Schamberg Aff.” refers to the May 15, 2013 Affidavit of Debra Schamberg, RN, filed in a prior Tennessee state court action, and which can be found at Docket No. 2469-2.

On August 19, 2015, the PSC issued a Rule 45 subpoena to O’Neal for both documents and deposition testimony. Docket No. 2438 at 7. O’Neal advised the PSC that he objected to the subpoena on the grounds that it sought privileged information and was overly broad. *Id.*; *see also* Docket No. 2478 at 1. On November 24, 2015, the PSC filed the instant motion seeking an order compelling O’Neal to comply with the subpoena. Docket No. 2437. O’Neal filed a motion for a protective order on December 4, 2015 and a response to the PSC’s motion on December 9, 2015. Docket Nos. 2469, 2478. In his response, O’Neal agrees to a deposition on the following topics: (1) questions about the contracts between STOPNC and O’Neal; (2) question about when the contracts were effective; (3) questions about alleged inconsistencies between the testimony of any witness and the contracts; and (4) questions about any recommendation made by O’Neal prior to STOPNC’s purchase of any particular medication. Docket No. 2478 at 2. He also agreed to provide a privilege log. *Id.* at 3.

The STOPNC Defendants<sup>4</sup> filed a brief opposing O’Neal’s deposition. Docket No. 2492. Specifically, the STOPNC Defendants argue that the Quality Improvement Committee Privilege is retroactive. *Id.* at 2, n. 5.

The Court heard oral argument on December 17, 2015.

## II. ANALYSIS

O’Neal’s main objection to the subpoena is that it seeks privileged information. There are two potentially applicable privileges here: (1) the Peer Review Privilege, which was in effect through April 12, 2011, *see* Tenn. Code Ann. § 63-6-219; and (2) the Quality Improvement Committee Privilege, which has been in effect since April 12, 2011, *see* Tenn. Code Ann. §§ 68-

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<sup>4</sup> The “STOPNC Defendants” refers to Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; and Vaughan Allen, MD.

11-272 and 63-1-150.<sup>5</sup> For the following reasons, the Court finds that O’Neal and the STOPNC Defendants have failed to show that the Peer Review Privilege applies. The Court reserves ruling on whether the Quality Improvement Committee Privilege applies to some or all of O’Neal’s activities.

**A. Standard Of Review**

The party claiming the protection of a privilege bears the burden of demonstrating, by a fair preponderance of the evidence, not only that the privilege applies, but also that it has not been waived.<sup>6</sup> In re Keeper of the Records (Grand Jury Subpoena Addressed to XYZ Corp.), 348 F.3d 16, 22 (1st Cir. 2003). Once a party claiming privilege has carried its initial burden of establishing grounds for asserting the privilege and that the privilege has not been waived, the burden shifts to the opposing party to establish any exceptions to the privilege. Vicor Corp. v. Vigilant Ins. Co., 674 F.3d 1, 17 (1st Cir. 2012).

**B. Applicable Law**

Analysis of the law of privileges begins with Rule 501 of the Federal Rules of Evidence. Rule 501 of the Federal Rules of Evidence provides, in relevant part that “. . . in a civil case, state law governs privilege regarding a claim or defense for which state law supplies the rule of decision.” Fed. R. Evid. 501. All of the pending claims at issue here are state tort claims. Thus,

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<sup>5</sup> Aside from some small differences, both statutes are essentially the same. For ease of reference, the Court will cite to Tenn. Code Ann. § 68-11-272.

<sup>6</sup> The Peer Review Privilege is held by all persons participating in the peer review process and individuals participating in the peer review process may not unilaterally waive it. Powell v. Community Health Systems, Inc., 312 S.W.3d 496, 513 (Tenn. 2010). There appears to be no caselaw on who holds the more recently created Quality Improvement Committee Privilege.

state privilege law applies to this matter. For purposes of this motion, the parties agree that Tennessee law applies.<sup>7</sup> Docket No. 2438 at 8; Docket No. 2469 at 8-9.

C. The Tennessee Peer Review Privilege

The Tennessee Peer Review Privilege (“PRP”) “applies only to peer review proceedings before a peer review committee as defined in Tenn. Code Ann. § 63-6-219(c) that involve a physician’s conduct, competence, or ability to practice medicine.” Lee Medical, Inc. v. Beecher, 312 S.W.3d 515, 526 (Tenn. 2010). It covers records possessed by entities that qualify as peer review committees but only when those entities are performing a peer review function. Id. at 536. Records kept by a hospital in the regular course of business unrelated to a peer review function involving a physician’s professional conduct, competence, or ability to practice medicine are not protected by the PRP. Id. Similarly, the PRP does not apply to “records in the custody of original sources who did not prepare the record for use by a peer review committee in a peer review proceeding.” Id.

In determining whether the privilege applies, the Court should apply a two-step analysis. Powell v. Community Health Systems, Inc., 312 S.W.3d 496, 504 (Tenn. 2010). First, the Court must determine whether “the subject matter of the underlying proceeding is within the subject matter covered by the statute.” Id. Second, the Court must determine whether the person or entity from whom the information is sought is a person or entity protected by the statute. Id. “If the answer to either question is ‘no,’ then the information being sought is not privileged, and the court should deny the invocation of the privilege and permit the discovery of the information

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<sup>7</sup> The PSC has argued that Massachusetts law governs these cases, while the Tennessee clinic defendants have argued that Tennessee law applies. The District Court has taken the issue under advisement. However, for purposes of this motion only, the PSC assumes Tennessee law applies. See Docket No. 2438 at 8, n. 16.

being sought.” Id. If, however, the answer to both questions is yes, then the Court should proceed to address the other specific disputes regarding the invocation of the PRP that may have been raised. Id.

The Court finds that O’Neal and the STOPNC Defendants have failed to show that the PRP applies here. First, they have not identified a “peer review committee” during the relevant time period or established that such committee meets the requirements of Tenn. Code Ann. § 63-6-219(c). Second, there is no evidence that any of O’Neal’s activities involved the evaluation and review of a physician’s professional conduct, competence, and ability to practice medicine. Neither the duties listed in the 2007 Contract, which was the contract in effect when the PRP was repealed, nor the duties described in the affidavits submitted support application of the PRP.

#### D. The Tennessee Quality Improvement Committee Privilege

Effective April 12, 2011, Tennessee repealed the PRP privilege and enacted the Quality Improvement Committee Privilege (“QICP”), Tenn. Code Ann. § 68-11-272. The QICP protects from disclosure “records of a [Quality Improvement Committee (“QIC”)] and testimony or statements by a healthcare organization’s officers, directors, trustees, healthcare providers, administrative staff, employees or other committee members or attendees relating to activities of the QIC.” Tenn. Code Ann. § 68-11-272(c)(1). A QIC is defined as:

. . . a committee formed or retained by a healthcare organization, an activity of a healthcare organization, or one (1) or more individuals employed by a healthcare organization performing the types of functions listed in subdivisions 4(A)-(P), the purpose of which, or one (1) of the purposes of which is to evaluate the safety, quality, processes, costs, appropriateness or necessity of healthcare services by performing functions including, but not limited to:

(A) Evaluation and improvement of the quality of healthcare services rendered;

- (B) Determination that the health services rendered were professionally indicated or were performed in compliance with the applicable standards of care;
- (C) Determination that the cost of health care rendered was reasonable;
- (D) Evaluation of the qualifications, credentials, competence and performance of healthcare providers or actions upon matters relating to the discipline of any individual healthcare provider;
- (E) Reduction of morbidity or mortality;
- (F) Establishment and enforcement of guidelines designed to keep the cost of healthcare within reasonable bounds;
- (G) Research;
- (H) Evaluation of whether facilities are being properly utilized;
- (I) Supervision, education, discipline, admission, and the determination of privileges of healthcare providers;
- (J) Review of professional qualifications or activities of healthcare providers;
- (K) Evaluation of the quantity, quality and timeliness of healthcare services rendered to patients;
- (L) Evaluation, review or improvement of methods, procedures or treatments being utilized;
- (M) Participation in utilization review activities, including participation in review activities within the facility or hospital system and activities in conjunction with an insurer or utilization review agent under title 56, chapter 6, part 7;
- (N) The evaluation of reports made pursuant to § 68-11-211 and any internal reports related thereto or in the course of healthcare organization's patient safety and risk management activities;
- (O) Activities to determine the healthcare organization's compliance with state or federal regulations;
- (P) Participation in patient safety activities as defined in § 921 of the Patient Safety and Quality Improvement Act of 2005.

Tenn. Code Ann. §68-11-272(b)(4).

1. Whether Issue Preclusion Bars The PSC From Litigating This Issue

One of the plaintiffs in the MDL, Wayne Reed, originally filed suit in Tennessee state court. Gastel Aff. at ¶ 4.<sup>8</sup> In that action, Reed moved to compel STOPNC to produce information over which STOPNC claimed the QICP privilege applied. *Id.* The Tennessee state

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<sup>8</sup> "Gastel Aff." refers to the Declaration of Benjamin A. Gastel in Support of Plaintiffs' Steering Committee's Motion to Compel Compliance with Subpoena to Micheal O'Neal. Docket No. 2439.

court found that the documents sought by Reed were protected by the QICP and denied Reed's motion to compel. See Docket No. 2469-3. Reed filed a notice of voluntary dismissal, which the Tennessee state court granted. Gastel Aff. at ¶ 11. Reed refiled the suit in the U.S. District Court for the Middle District of Tennessee, and the case was transferred and consolidated into this MDL. Id. The STOPNC Defendants argue that the doctrine of issue preclusion or collateral estoppel bars the PSC from litigating this issue again in this MDL. The Court disagrees.

Federal courts must "give the same preclusive effect to state court judgments that those judgments would be given in the courts of the State from which the judgments emerged." Cruz v. Melecio, 204 F.3d 14, 18 (1st Cir. 2000) (citation omitted). Under Tennessee law, the party invoking issue preclusion has the burden of proof. Mullins v. State, 294 S.W.3d 529, 535 (Tenn. 2009) (citations omitted). To prevail on an issue preclusion claim, the party asserting it must show:

(1) that the issue to be precluded is identical to an issue decided in an earlier proceeding, (2) that the issue to be precluded was actually raised, litigated, and decided on the merits in the earlier proceeding, (3) that the judgment in the earlier proceeding has become final, (4) that the party against whom collateral estoppel is asserted was a party or is in privity with a party to the earlier proceeding, and (5) that the party against whom collateral estoppel is asserted had a full and fair opportunity in the earlier proceeding to contest the issue now sought to be precluded.

Id. "Moreover, in order for the doctrine of collateral estoppel to apply, the issue must not only have been actually litigated and decided, it must also have been necessary to the judgment." Id. (citations omitted). "Determinations of an issue or issues that are not necessary to a judgment have the characteristic of dicta and will not be given preclusive effect." Id.

Here, several of the requirements for issue preclusion are not met. First, the state court's decision was not final and was not subject to appeal. A discovery order is an interlocutory order subject to appeal only upon application and in the discretion of the trial and appellate court. See

Tenn. R. App. Proc. 9(a). In addition, the case was voluntarily dismissed, the effect of which “is to render the proceedings a nullity and leave the parties as if the action had never been brought.”

National R.R. Passenger Corp. v. Int’l Ass’n of Machinists and Aerospace Workers, 915 F.2d 43, 48 (1st Cir. 1990).<sup>9</sup> Second, the trial court’s decision would not have been necessary to a judgment on the merits in the Tennessee case. Finally, neither the PSC nor the individual plaintiffs in this MDL (other than Reed) had any opportunity to litigate the issue of claims of privilege related to O’Neal in the state court litigation. Accordingly, the Court finds that issue preclusion does not apply.

## 2. Whether The QICP Applies Retroactively

While O’Neal himself does not contend that the QICP applies retroactively, the STOPNC Defendants do. Compare Docket No. 2478 at 2 with Docket No. 2492 at 1. Statutes are presumed to operate prospectively unless the legislature clearly indicates otherwise. Nutt v. Champion Int’l Corp., 980 S.W.2d 365, 368 (Tenn. 1998). Here, the statute does not clearly indicate that it applies retroactively.

However, statutes that are remedial or procedural apply retroactively to causes of action arising before such acts became law and to suits pending when the legislation took effect. Id. “A procedural or remedial statute is one that does not affect the vested rights or liabilities of the parties.” Id. (citation omitted). “A procedural statute is one that addresses the mode or proceeding by which a legal right is enforced.” Id. (citation omitted). “Remedial statutes are defined as ‘[l]egislation providing means or method whereby causes of action may be effectuated, wrongs redressed and relief obtained . . .’” Id. (citation omitted). Remedial statutes

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<sup>9</sup> The parties have not cited and this Court is not aware of any Tennessee caselaw on this particular point.

also include legislation “passed to correct or modify an existing law” and as “a law that gives a party a new or different remedy when the existing remedy, if any, is inadequate.” In re D.A.H., 142 S.W.3d 267, 273 (Tenn. 2004).

The STOPNC Defendants argue that the QICP statute is remedial in that it was enacted to remedy the Supreme Court of Tennessee’s decision in Lee. To support this argument, however, the STOPNC Defendants cite only to articles written by law firms representing some of the defendants in this MDL. Docket No. 2492 at 2, n. 5. At oral argument, counsel for the STOPNC Defendants represented that he had not cited to any other sources because he believed this point was not seriously in dispute. If the STOPNC Defendants wish the Court to consider this argument, they shall file further support, including the relevant legislative history, if any, within two weeks of the date of this Order.<sup>10</sup>

### 3. Whether The Documents And Testimony Are Protected By the QICP

Even if the Court were to find that the QICP applies retroactively, the information provided by the STOPNC Defendants is not sufficient to determine whether the QICP privilege applies to all or some of O’Neal’s activities as STOPNC’s consultant. Among other things, questions remain regarding the execution of the 2012 Contract and O’Neal’s duties. Therefore, the Court will allow O’Neal’s deposition to go forward on the following topics: (1) questions about the contracts between STOPNC and O’Neal and O’Neal’s duties pursuant to those contracts; (2) questions about when the contracts were effective; and (3) questions about the alleged inconsistencies between the testimony of any witness and the contracts. If the PSC still

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<sup>10</sup> The Court notes that, on December 21, 2015, the STOPNC Defendants filed a motion to file a supplemental brief on this point among other issues. The Court grants that motion today. STOPNC need not file anything further if it so chooses but has the opportunity to do so in the next two weeks.

contends that the QICP does not apply after taking the deposition, it shall file a further brief within two weeks after completion of the deposition. The STOPNC Defendants shall file a response, if any, within two weeks after the PSC's filing. The Court reserves a ruling on this issue pending further briefing.

E. The Request For Documents Is Overly Broad

The PSC seeks "all documents related to [NECC]" and "all documents related to Depo Medrol and/or a generic equivalent and/or methylprednisolone acetate" for the period January 1, 2000 to September 30, 2012. Docket No. 2469 at 18. The request is overly broad. Consistent with the Court's recollection of the PSC's agreement at the hearing, the request for documents shall be limited to documents regarding O'Neal's evaluation of NECC and/or regarding the purchase of MPA from NECC for the period from January 1, 2007 to September 30, 2012. O'Neal must provide a privilege log for any documents he claims are privileged within fourteen days of the date of this Order.

III. ORDER

For the foregoing reasons, the Court grants in part and denies in part the parties' motions. The Court finds that O'Neal and the STOPNC Defendants have failed to show that the Peer Review Privilege applies to the documents and testimony sought. The Court reserves ruling on the issue of whether the Quality Improvement Committee Privilege applies to all or some of O'Neal's activities pending further briefing after O'Neal's deposition.

/s/ Jennifer C. Boal  
JENNIFER C. BOAL  
United States Magistrate Judge